

REMARKS

Claims 1-11, 13, 15-17, 19, 22, 25, 26 and 28 are currently pending in this National Stage application, the remaining claims (12, 14, 18, 20, 21, 23, 24 and 27) having been canceled in the "Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Filing Under 35 U.S.C. 371," which was submitted at the time of filing.

Applicants hereby elect, with traverse, to prosecute Group II, which includes and is drawn to claims 3-7, 9, and 11. Further, Applicants elect, with traverse, to prosecute claims related to the polynucleotide sequences encoding the polypeptide sequence of SEQ ID NO:8, which sequences include SEQ ID NO:30, and which sequences read on claims 3-7, 9, and 11. Applicants traverse both the restriction requirement and the obligation to elect a single sequence for prosecution which were imposed in the Office Action mailed June 24, 2002 for at least the following reasons.

Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications.

The unity of invention standard *must* be applied in national stage applications

Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides:

... [W]hen the Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111....

In applying PCT Rule 13.2 to ... national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2....

Id at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

Examiners are reminded that unity of invention (not restriction) practice is applicable ... in national stage (filed under 35 U.S.C. 371) applications.

Id at page 1800-149, column 1.

Specific provisions of the Administrative Regulations Under the PCT and the corresponding provisions of the MPEP strongly support a finding of unity of invention among all of the claims in the present case

Unity of Invention is accepted as between claims to polypeptide sequences and claims to the polynucleotide sequences which encode them

Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT provides that unity of invention is accepted as between claims to polypeptide sequences and claims to polynucleotide sequences encoding those polypeptides. Those Examples are cited in MPEP section 1893.03(d) at page 1800-149, column 2 (“[n]ote also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions...”)

Thus, in the present case, unity of invention exists at least as between claims drawn to polypeptide sequences SEQ ID NO:1-22 (*i.e.*, claims 1, 2, 16 and 17) and as to claims drawn to polynucleotide sequences which encode those polypeptides (*i.e.*, claims 3-6 and 11).

Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to claims 1-6, 11, 16 and 17, and examine those claims in a single application.

Unity of invention exists with respect to dependent claims in the same claim category as the independent claim from which they depend

MPEP section 1850(A) and 1893.03(d), which recite the provisions of paragraph (c) of Part 1 (entitled “Instructions Concerning Unity of Invention”) of Annex B (entitled “Unity of Invention”) to the Administrative Instructions Under the PCT, provides:

(A) Independent and Dependent Claims.

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By “dependent” claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression “category of claim” referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).

(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention....

See MPEP section 1850(A) at page 1800-61. See also MPEP Appendix AI at page 53.

In the present case, claims 2-8, 16 and 17, all of which depend from claim 1, are all directed to compositions of matter, *i.e.*, to products. All of these claims contain all of the features of the independent claim. Further, as discussed above, there is unity of invention as between claim 1 and claim 11. Finally, both claim 1 and claim 11 avoid the prior art, as discussed below.

Thus, it is improper to restrict claims 1, 2, 16 and 17 from claims 3-8 and 11, as the Examiner has done. Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to the composition of matter claims, and that at least those claims be considered together in a single application.

Unity of invention exists as between all of Applicants' claims

MPEP 1850 provides:

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Id at page 800-61.

MPEP 1893.03(d) similarly provides:

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

Id at page 1800-149.

In the present case, unity of invention exists among all of Applicants' claims. The claimed polypeptide sequences and the claimed polynucleotide sequences encoding them are corresponding technical features which are common to all of Applicants' claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application.

The claimed polypeptide sequences, and the claimed polynucleotide sequences encoding those polypeptide sequences, are corresponding technical features that are common to all of Applicants' claims and that serve to technically interrelate them

Applicants' claims recite *inter alia* the polypeptides SEQ ID NO:1-22, and polynucleotides encoding those polypeptides, which sequences include the polynucleotide sequences SEQ ID NO:23-44. See Table 1 of the specification. Applicants respectfully submit that the claimed polypeptide sequences SEQ ID NO:1-22, and the claimed polynucleotide sequences encoding them, are corresponding technical features, given that the former are encoded by the latter, and conversely, the latter encode the former.

Further, the claimed polypeptide and corresponding polynucleotide sequences are common to all of Applicant's claims, given that each claim refers to one or both either explicitly or implicitly, by virtue of depending from a claim which makes an explicit reference to the claimed sequences.

Moreover, the claimed polypeptide and corresponding polynucleotide sequences serve to technically interrelate all of Applicants' claims. Applicants' composition of matter claims (1-8, 10, 11, 16 and 17) are drawn to either the sequences themselves (1 and 2, drawn to polypeptide sequences, and 3-5 and 11, drawn to polynucleotide sequences), to compositions of matter which comprise the sequences as one element (6-8, drawn to recombinant polynucleotide sequences, transformed cells, and transgenic organisms, respectively, and 16 and 17, drawn to pharmaceutical compositions), or to compositions of matter wherein the claimed sequences functionally limit the claimed subject matter (claim 10, drawn to antibodies which specifically bind a polypeptide of claim 1).

In Applicants' method claims 9, 13, 15, 19, 22, 25, 26 and 28), the claimed sequences serve as either the product of the claimed method (claim 9, drawn to a method of polypeptide production)

and/or as a reagent for performing the method (claims 19, 22, 25 and 26, drawn, respectively, to methods of screening for agonists, ant-agonists, compounds which specifically bind, or compounds which modulate the activity of, a polypeptide of claim 1; and claims 13, 15, and 28, drawn, respectively, to methods of detecting a target polynucleotide in a sample, and to a method for assessing toxicity of a test compound).

Therefore, the claimed polypeptide and polynucleotide sequences are corresponding technical features which are common to all of Applicants' claims, and which serve to technically interrelate them.

This fact is recognized by the Examiner: "[t]he technical feature linking Groups I-XIV appears to be the claimed amino acid/nucleic acid sequences." See page 3 of the Office Action under consideration. It is also implicitly recognized and admitted by the Examiner's statement that "... the technical feature linking the inventions of Groups I-XIV does not constitute a *special* technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art" [emphasis added]. See the current Office Action at page 4. (As to the Examiner's assertion regarding whether the polypeptides and corresponding polynucleotides linking all of Applicants' claims define a contribution over the prior art, see the discussion appearing below.)

The claimed polypeptide and polynucleotide sequences define the contribution made by each of Applicants' claims over the prior art: the 35 U.S.C. § 102(b) rejection

Contrary to the Examiner's assertion, the polypeptide and polynucleotide sequences claimed by Applicants are themselves contributions over the prior art, and they therefore define the contribution made over the prior art by all of Applicants' other claims.

At page 4, lines 3-5 of the Office Action currently under consideration, the Examiner has alleges that "the technical feature linking the inventions of Groups I-XIV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art." The Examiner reasons as follows: (1) the technical feature linking Groups I-XIV is, the claimed amino acid/nucleic acid sequences; (2) the sequences disclosed by the cited references (Seol *et al.* and by Straussberg *et al.*) *allegedly* teach polypeptide fragments of SEQ ID NO:1; (3) the reference sequences anticipate the claimed amino acid/nucleic acid sequences; and therefore, (4) the claimed amino acid and nucleic acid sequences do not define a contribution over the prior art.

Applicants respectfully disagree with the Examiner's reasoning. Applicants first wish to emphasize that it is those polypeptide sequences and/or those corresponding polynucleotide sequences in their *entire* form which provide the "common or corresponding special technical feature" linking all of the claims to form a single general inventive concept.

Applicants respectfully point out that the full-length polypeptide and corresponding full-length polynucleotide sequences recited in claims 1 and 11 in their current form, and the claims dependent thereon, are not anticipated by the sequences described by the cited references. First, none of the full-length polypeptide or polynucleotide sequences recited in claim 1 or claim 11 as they are currently pending are explicitly disclosed by either of the cited references. See the enclosed sequence alignments. Moreover, even assuming for purposes of argument that the reference sequences disclose polypeptide fragments which exhibit sequence identity with *fragments* of SEQ ID NO:1, neither SEQ ID NO:1 itself, nor any polynucleotide sequence which encodes SEQ ID NO:1, can be anticipated by those fragments. Therefore, the contribution over the prior art represented by the full-length polypeptide and polynucleotide sequences is not negated by the cited references.

In sum, the claimed polypeptide sequences and the claimed polynucleotide sequences which encode them are corresponding technical features which are common to all of Applicants' claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application. Withdrawal of the restriction requirement in the present case is therefore respectfully requested.

The Election of Species Requirement

Applicants elect, with traverse, to prosecute claims related to the polynucleotide sequences encoding the polypeptide sequence of SEQ ID NO:8, which sequences include SEQ ID NO:30. Those polynucleotide sequences read on claims 3-7, 9, 11, and 12. Applicants traverse the Election of Species Requirement for at least the following reasons.

With respect to those polynucleotides other than SEQ ID NO:23 which encode amino acid sequence of SEQ ID NO:1, MPEP 1850 provides, in the section entitled "Unity of Invention -

Nucleotide Sequences,” that “[n]ucleotide sequences encoding the same protein are considered to satisfy the unity of invention standard and will continue to be examined together.” See page 1800-65, column 1.

With respect to the polynucleotide sequences encoding the amino acid sequences of SEQ ID NOS:2-22 (*i.e.*, sequences which include SEQ ID NO:24-44), section D of MPEP section 1850, which recites the provisions of paragraph (f) of Part 1 (entitled “Instructions Concerning Unity of Invention”) of Annex B (entitled “Unity of Invention”) to the Administrative Instructions Under the PCT, provides:

D. “Markush Practice”

The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a **common property or activity; AND**

(B)(1) A common structure is present, *i.e.*, a **significant structural element is shared by all of the alternatives; OR**

(C)(2) In cases where the common structure cannot be the unifying criteria, **all alternatives belong to a recognized class of chemical compounds** in the art to which the invention pertains.

(ii) In paragraph (B)(1), above, the words “significant structural element is shared by all of the alternatives” refer to cases where the compounds share a **common chemical structure which occupies a large portion of their structures**, or in case the compounds have in common only a small portion of their structures, the commonly shared structure **constitutes a structurally distinctive portion** in view of existing prior art. The structural element may be a **single component OR a combination of individual components linked together**.

(iii) In paragraph (C)(2), above, the words “recognized class of chemical compounds” mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

(iv) The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.

(v) When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised.

See MPEP at pages 1800-61 to -62.

In the present case, several of the polypeptide sequences claimed by Applicants are alternatives of a similar nature, and should therefore be examined in a single application.

Applicants respectfully submit that SEQ ID NOS: 15 and 16 are alternatives of a similar nature in that all have been identified by Applicants as transmembrane G protein-coupled receptor proteins (hereinafter "GPCRs") on the basis of their exhibiting significant sequence homology to known GPCRs and/or on the basis of the presence of certain characteristic signature sequences, motifs and domains. See Table 2 of Applicants' specification. As such, they share the common property/activity of being transmembrane proteins involved in signal transduction.

The preceding sequences also share significant structural elements, in that all of these sequences exhibit one or more G protein-coupled receptor signatures. In particular, a seven transmembrane helical motif is characteristic of the GPCR superfamily (in this regard, see Kuipers, *et al.*, Receptors Channels 5:159-174 (1997) (abstract enclosed)). This motif is present in both polypeptide sequences.

In the alternative, the polypeptide sequences claimed by Applicants satisfy the second prong of the PCT test, given that both of them belong to a recognized class of chemical compounds in the art, *i.e.*, GPCR's.

Therefore, SEQ ID NOS: 15 and 16 are alternatives of a similar nature which should be examined together in a single application.

Applicants respectfully submit that SEQ ID NOS:10 and 12 are also alternatives of a similar nature in that they have all been identified by Applicants as T-cell receptor alpha chains on the basis of their exhibiting significant sequence homology to known T-cell receptor alpha chains (both SEQ ID NO:10 and SEQ ID NO:12), and on the basis of the presence of certain characteristic signature sequences, motifs and domains. In particular, both polypeptide sequences possess an immunoglobulin domain, and SEQ ID NO:12 further possesses a T-cell receptor alpha chain signature, as well as a T-cell surface antigen domain. See Table 2 of Applicants' specification. As such, they share the common property/activity of being T-cell membrane receptors, and they share the common significant structural element of an immunoglobulin domain.

Therefore, SEQ ID NOS:10 and 12 are alternatives of a similar nature which should be examined together in a single application.

Therefore, Applicants respectfully request that the Examiner withdraw the Election of Species requirement, and examine together those claims which relate to SEQ ID NO:15 and SEQ ID NO:16, or in the alternative, those claims which relate to SEQ ID NO:10 and SEQ ID NO:12.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 1 has been amended as follows:

1. An isolated polypeptide comprising an amino acid sequence selected from the group consisting of:

a) an amino acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:20, and SEQ ID NO:22, and

b) a naturally occurring amino acid sequence having at least 90% sequence identity to an amino acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:20, and SEQ ID NO:22,

c) a biologically active fragment of an amino acid sequence selected from the group consisting of [SEQ ID NO:1,]SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:20, and SEQ ID NO:22, and

d) an immunogenic fragment of an amino acid sequence selected from the group consisting of [SEQ ID NO:1,]SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:20, and SEQ ID NO:22.